



EXPRESS MAIL CERTIFICATE - LABEL NO EL 168 022 554 US

I hereby certify that this correspondence is being deposited with the United States EXPRESS MAIL Service as Express Mail in an envelop addressed to: Commissioner for Patents, Washington, D. C. 20231 on November 12, 2002.

By: Ruth Montalvo

Date: November 12, 2002

In the event that this paper is late filed and a necessary Petition for an Extension of Time is not concurrently filed herewith, please consider this as a Petition for the requisite extension of time, and to the extent not tendered by check attached hereto, authorization to charge the extension fee.

JG-RP-4796CPA/500561.20065

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Claudia Cherney STEWART Group: 1617
Serial No.: 09/330,629 Examiner: S. HUI
Filing Date: June 11, 1999 Customer No: 026418
For: METHOD OF HIV AND HPV PROPHYLAXIS

Commissioner for Patents
Washington, D. C. 20231

PRELIMINARY AMENDMENT

Sir:

Prior to examination of the above-identified application on the merits, please amend the above-identified application as follows:

Please cancel claims 1-14 and add new claims 41-53 as follows:

41. (new) A method for prophylactically reducing the risk of transmission of Human Immunodeficiency Virus infection to a recipient and protecting the recipient from infection with Human Immunodeficiency Virus infection comprising topically applying a Human Immunodeficiency Virus infection prophylactic effective amount to that site on the recipient which is likely to be exposed to Human Immunodeficiency Virus infection a composition comprising a Human Immunodeficiency Virus infection prophylactic effective amount of a compound having the structure

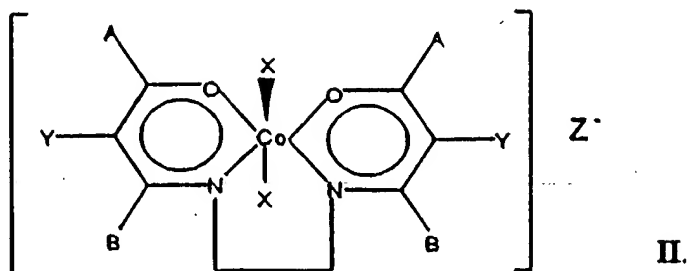
TECHNICAL CENTER 1600/290

NOV 15 2002

RECEIVED

#20/C
HUI
11/20/02

51



wherein each

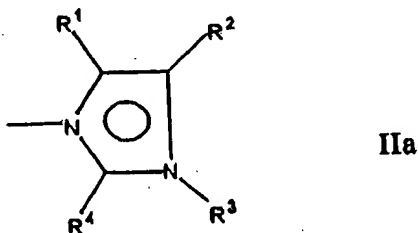
A is the same or different and is an alkyl group, a phenyl group or a substituted derivative of a phenyl group;

Y is the same or different and is hydrogen, an unbranched alkyl group, a halide or a group having the structure $\text{R}-\text{C}(=\text{O})-$ wherein R is hydrogen, an alkoxide group, an alkyl group, or OH;

B is the same or different and each is hydrogen or an alkyl group;

Z^- is a soluble, pharmaceutically acceptable negative ion; and

X is the same or different and is an axial ligand selected from the group consisting of moieties having the formula:



wherein R^1 , R^2 , R^3 and R^4 are the same or different and may be hydrogen or lower alkyl having from 1 to 4 carbon atoms;

DI

with the proviso that R^1 , R^2 , R^3 and R^4 are of a sufficiently small size so as not to prohibit the attachment of the axial ligand to the Co atom due to steric hindrance.

42. (new) The method of claim 41 wherein the compound is from about 0.00005 to about 5% by weight of the composition.

*Co
cont*

43. (new) The method of claim 41 wherein the compound is from about 0.005 to about 5% by weight of the composition.

44. (new) The method of claim 41 wherein the compound is from about 0.005 to about 2% by weight of the composition.

45. (new) The method of claim 41 wherein the compound is from about 0.01 to about 2% by weight of the composition.

46. (new) The method of claim 41 wherein the composition is in the form of a pharmaceutically acceptable saline solution, ointment, salve or crème.

47. (new) The method of claim 41 wherein the composition is applied intravaginally.

48. (new) The method of claim 41 wherein the composition is applied from about 1 hour before to about 6 hours after the exposure to the Human Immunodeficiency Virus.

49. (new) The method of claim 41 wherein the composition is applied from about 5 minutes before to about 5 minutes after exposure to the Human Immunodeficiency Virus.

50. (new) The method of claim 41 wherein the Human Immunodeficiency Virus is HIV-1 or HIV-2.

51. (new) the method of claim 41 wherein the compound is Compound 96.

52. (new) The method of claim 41 wherein the step of topically applying the composition is performed by contacting the subject with an applicator coated with the composition.

53. (new) The method of claim 52 wherein the applicator is a condom.

In view of the foregoing, it is submitted that this application is in condition for allowance and favorable reconsideration and prompt notice of allowance are earnestly solicited.

Respectfully submitted,
REED SMITH, LLP

November 12, 2002
599 Lexington Avenue, 29th Floor
New York, NY 10022
Tel. (212) 521-5403
JEG:dej

By: 
Jules E. Goldberg - Reg. No. 24,408